

K062352

**510(k) Summary**

(As required by 21 CFR 807.92 and 21 CFR 807.93) OCT 19 2006

**NAME OF SPONSOR:** DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46582  
Establishment Registration Number: 1818910

**510(K) CONTACT:** Rebecca Lennard  
Regulatory Affairs Associate II  
Telephone: (574) 372-5023  
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**DATE PREPARED:** May 24, 2006

**PROPRIETARY NAME:** FRS® Screw

**COMMON NAME:** Bone Fixation Screw

**CLASSIFICATION:** Class II device per 21 CFR 888.3040: Smooth or threaded bone fixation fastener

**DEVICE PRODUCT CODE:** 87 HWC

**SUBSTANTIALLY EQUIVALENT DEVICES:** DePuy SCARF THREAD-HEAD™ SCREW, K962236, cleared on September 20, 1996  
NewDeal SA BOLD® Screw, K011262, cleared on June 15, 2001

**DEVICE DESCRIPTION:**

The DePuy FRS-Screw is a cannulated thread-head screw made of a Titanium alloy and is available in lengths of 10-34mm in 2mm increments.

**INTENDED USE AND INDICATIONS:**

**Intended Use:**

The DePuy FRS-Screw is intended to be implanted for the fixation of bone fractures, fusion of a joint or bone reconstructions.

**Indications for Use:**

The FRS®-Screw is indicated for fixation of bone fractures, fusion of a joint, or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals, and carpals of the hand. Examples include:

- Hallux Valgus correction
- Akin Osteotomies

- MTP arthrodesis
- Interphalangeal arthrodesis

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy FRS®-Screw devices described in this submission are substantially equivalent to the predicate devices based on similarities in intended use, indications for use, materials and design.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DePuy Orthopaedics, Inc.  
% Ms. Rebecca Lennard  
700 Orthopaedic Drive  
Warsaw, Indiana 46582

OCT 19 2006

Re: K062352

Trade/Device Name: FRS® Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: August 10, 2006  
Received: August 11, 2006

Dear Ms. Lennard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

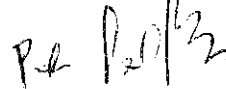
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510 (k) Number (if known): \_\_\_\_\_

Device Name: FRS®-Screw

### **Indications for Use:**

The **FRS®-Screw** is indicated for fixation of bone fractures, fusion of a joint, or bone reconstruction (osteotomy) of the mid-foot bones, metatarsal and phalanges of the foot or the phalanges, metacarpals, and carpals of the hand. Examples include:

- Hallux Valgus correction
- Akin Osteotomies
- MTP arthrodesis
- Interphalangeal arthrodesis

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: x OR Over-The-Counter-Use: \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** 16062257